

APPLICATION FOR A MANUFACTURER/WHOLESALE DISTRIBUTOR

Authority: 1978 PA 368

Type or Print Clearly

| | | | |
|------------------------------------------------|-------|-----------------------------------------------------------------|--|
| Name of Facility (Assumed Name, if applicable) | | Entity Name | |
| Contact Person | | Phone Number | |
| Facility Address | | Email Address | |
| City | State | Zip Code | |
| State of Incorporation | | Federal Employer I.D. Number | |
| Proposed Date of Opening | | Michigan 10-Digit Permanent ID / License Number (if applicable) | |

Relocation Only:

| | | | |
|-----------------------------|-------|------------------|--|
| New Facility Address | | New Phone Number | |
| City | State | Zip | |
| Proposed Date of Relocation | | | |

| CHECK THE LICENSE/OBTAINED BY METHOD | FOR OFFICE USE ONLY | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------|
| <input type="checkbox"/> New Manufacturer/Wholesale Distributor \$88.40 71-5306-01 <input type="checkbox"/> Change of Location Manufacturer/Wholesale Distributor \$88.40 71-5306-01 <input type="checkbox"/> Relicensure Manufacturer/Wholesale Distributor \$108.40 71-5306-01 <input type="checkbox"/> Controlled Substance License \$88.40 71-5306-3757 Your check or money order, drawn from a U.S. financial institution and made payable to the STATE OF MICHIGAN , must accompany this request. DO NOT SEND CASH. Fees are non-refundable. | Facility License Number | Issue Date |
| | Controlled Substance License Number | Issue Date |
| | | |

Facility Operation and Ownership

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| Type of Operation <input type="checkbox"/> DME Provider for devices salable on prescription <input type="checkbox"/> Full Service Wholesaler <input type="checkbox"/> Import/Export <input type="checkbox"/> Repackager <input type="checkbox"/> Distribution <input type="checkbox"/> Buying Group <input type="checkbox"/> Manufacturer for Devices salable on prescription <input type="checkbox"/> Manufacturer for drugs salable on prescription <input type="checkbox"/> 3 rd Party Logistics <input type="checkbox"/> Virtual Manufacturer | Type of Ownership <input type="checkbox"/> Public Corporation <input type="checkbox"/> Private Corporation <input type="checkbox"/> Limited Liability Company <input type="checkbox"/> Partnership <input type="checkbox"/> Individual Owner |
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License(s) in Other State(s)

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| Does this facility/entity hold, or has it ever held, a license or registration for operation in any other state? <input type="checkbox"/> Yes <input type="checkbox"/> No | | |
| If yes, list each state, the license or registration number, and the date issued. (Attach additional sheets if necessary). If there are pending disciplinary proceedings and/or there have been sanctions imposed against a license or registration, documentation must be submitted as proof that sanctions are not in force or that there are not pending disciplinary proceedings at the time of this application. | | |
| State | Permanent License / Registration Number | Date of Issuance |
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Pharmacist in Charge / Facility Manager

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| Check the box next to the category that applies to this facility: <input type="checkbox"/> This is a manufacturer of drugs salable on prescription only that has designated a pharmacist licensed in or outside of Michigan as the Pharmacist in Charge for the manufacturer. <input type="checkbox"/> This is a wholesale distributor that has designated a pharmacist licensed in or outside of Michigan as the Pharmacist in Charge for the wholesale distributor or that has designated an employee with the appropriate education or experience, or both, to assume responsibility for compliance with licensing requirements as facility manager for the wholesale distributor. <input type="checkbox"/> This is a manufacturer or wholesale distributor with respect to a device salable on prescription only but not with respect to any drug salable on prescription only and is exempt from the Pharmacist in Charge or Facility Manager requirement. | | |
| Name of PIC | License Number | State of Licensure |
| Name of Facility Manager | | |

Facility Ownership

List the names and dates of birth of the individual owner; or, if a partnership, all partners and any individual who will manage the day-to-day operations; or, if applying as a privately held corporation, any individual who will manage the day-to-day operations.

(NOTE: This only applies to a privately held corporation that in the aggregate owns fewer than 75 pharmacies, manufacturers, or wholesale distributors on the date the corporation submits its license application.) Attach a separate sheet, if necessary.

For a corporation, list the name and title of each officer and director on a separate sheet and attach the list to this application. Corporation officers and directors do not need to be fingerprinted unless they are managing the day-to-day operations, as noted above.

| Name | Title | Date of Birth | Social Security Number |
|------|-------|---------------|------------------------|
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Criminal and Disciplinary History – Attach a detailed explanation for any “Yes” answers

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| 1. Has the applicant or any individual director, employee, officer, stockholder, facility manager or partner ever been convicted of a misdemeanor or a felony relating to controlled substances or the practice of pharmacy? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Has any individual director, officer, owner, stockholder, facility manager or partner ever had a financial interest in a pharmacy, manufacturer, or wholesale distributor which has: a. Been denied a license or federal registration? b. Had its license or federal registration limited, suspended, or revoked? c. Been subject to any other criminal, civil, or administrative penalty? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

All Applicants

NOTE: An application accompanied by the appropriate fee is valid for two years. If an applicant fails to complete the requirements for licensure within two years from the date of filing the application, the application is no longer valid.

In addition, manufacturers or wholesale distributors of any prescription drug or prescription device that are doing business in the State of Michigan, whether or not located in the State of Michigan, must be licensed by the Board of Pharmacy. If controlled substances are to be manufactured or distributed, the facility must also obtain a controlled substance license. Please check the appropriate boxes on the first page of the application and submit the appropriate fees.

A manufacturer or wholesale distributor that manufactures or distributes prescription drugs in this state from one or more locations in this state must obtain a separate license for each location in this state from which prescription drugs are manufactured or distributed. A separate application with all supporting documents must be filed for each location.

New Manufacturer/Wholesale Distributor or Change of Location

- The application must be completed in its entirety and returned to the Bureau with the appropriate fee(s).
- New Facilities Only:** The individuals listed below for a manufacturer/wholesale distributor license are required to undergo a Criminal Background Check (CBC) and provide evidence of fingerprint processing from an authorized agency. Upon review of the application, instructions for completing the Criminal Background Check

will be provided by the Bureau. **Do not proceed** with the fingerprinting process before receiving the fingerprint instructions and forms.

- a. An individual, if the person applying is an individual.
- b. All partners and any individual who will manage the day-to-day operations, if the person applying is a partnership.
- c. Any individual who will manage the day-to-day operations, if the person applying is a privately held corporation. This subdivision only applies to a privately held corporation that in the aggregate owns fewer than 75 pharmacies, manufacturers, or wholesale distributors on the date the corporation submits its license application.

An individual is not required to obtain a CBC if one has been obtained for the individual(s) within the 2 years preceding the date of application for a new pharmacy, manufacturer, or wholesale distributor license. If fingerprints have been obtained within the two years preceding the date of the application, the individual(s) must submit proof of the previous criminal history check with the application for a manufacturer/wholesale distributor license.

- Arrange for a verification and/or certification to be sent directly to the Michigan Board of Pharmacy from any state or province where the facility is currently or has ever held a permanent license or registration. **Copies of licenses are not acceptable.** Online verifications are acceptable if they show that there has been no discipline in that state or province.
- With the application, submit photographs of the interior and exterior premises and a floor plan of the area to be licensed, along with a description of the type of activities carried out in each building. **Do not send a copy of blueprints.** Applicants who handle controlled substances may submit a copy of their DEA registration in lieu of photographs and floor plan.
- If you are an outsourcing facility, you must apply as a pharmacy, not as a manufacturer/wholesale distributor.
- Manufacturers of drugs salable on prescription only must designate a pharmacist licensed in or outside of Michigan as the Pharmacist in Charge for the manufacturer. A wholesale distributor shall designate a pharmacist licensed in or outside of Michigan as the Pharmacist in Charge for the wholesale distributor or shall designate an employee with the appropriate education or experience, or both, to assume responsibility for compliance with licensing requirements as facility manager for the wholesale distributor. A person that is a manufacturer or wholesale distributor with respect to a device salable on prescription only but not with respect to any drug salable on prescription only is exempt from the Pharmacist in Charge/Facility Manager requirement.
- Applicants from businesses that are partnerships, corporations, or operating under an assumed name must file the application for a manufacturer/wholesale distributor license along with copies of:
 - a. Partnership Certificates
 - b. Articles of Incorporation
 - c. Assumed Name Certificates
- Provide a list or catalog of all drug products and/or devices salable upon prescription that are manufactured or distributed in Michigan.
- Complete the Compliance Checklist in its entirety.
- Complete the information on the application regarding the opening date, name of person to contact and telephone number.

Upon receipt of the required documentation, your application will be reviewed for compliance with the laws and rules of the Michigan Board of Pharmacy. If a satisfactory inspection and/or review is received, a permanent identification number will be assigned and the license(s) will be issued.

Sale or Transfer of a Manufacturer/Wholesale Distributor

- If a manufacturer or wholesale distributor is changing ownership, do not fill out this application. The new owner must fill out the Change of Ownership form on the Pharmacy website at www.michigan.gov/bpl.

Relicensure of a Manufacturer/Wholesale Distributor (Previously Licensed in Michigan)

- The application for manufacturer/wholesale distributor license should be completed in its entirety and returned to the Bureau with the appropriate fee(s).
- If the Michigan manufacturer/wholesale distributor license has been lapsed for more than 3 years, the applicant is required to complete the fingerprinting process as described in instruction #2 under Procedures for Obtaining a New Manufacturer/Wholesale Distributor License.
- Follow the other instructions as outlined under Procedures for Obtaining a new Manufacturer/Wholesale Distributor License.

DEA Information

You may also apply to the Drug Enforcement Administration (DEA) for registration under the Federal Controlled Substances Act at the same time you apply for the Board of Pharmacy license. A federal application may be obtained from the Department of Justice Drug Enforcement Administration, 431 Howard Street, Detroit, Michigan 48226. The telephone number is 1-800-882-9539. All questions concerning the federal license should be directed to that office.

CERTIFICATION AND SIGNATURE

I understand that it is the policy of this agency to secure a criminal conviction history as part of the pre-licensure screening process. I authorize this agency to use the information provided in this application to obtain a criminal conviction history file search from the Federal Bureau of Investigation, the Central Records Division of the Michigan Department of State Police, law enforcement, or judicial record-keeping organizations. I consent to the release of information regarding a disciplinary investigation conducted by a similar licensure, registration, or specialty licensure or specialty certification board of this or any other state, of the United States military, of the federal government, or of another country.

I certify that the statements in this application are true and complete. I understand that any omitted statement, misrepresentation, or fraud may be cause for denial of my application, disciplinary action, or may be punishable by law.

Printed Name of Authorized Representative of Owner

Signature of Authorized Representative of Owner

Date

COMPLIANCE CHECKLIST FOR MANUFACTURERS/WHOLESALE DISTRIBUTORS

Authority: Public Act 368 of 1978, as amended.
 If this form is not completed, a license will not be issued.

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| Name of Manufacturer/Wholesaler: | |
| Street Address: | Ste/Bldg.#: |
| City: | State: |
| Zip Code: | County: |
| Name of Contact Person | Phone Number: |
| Name of PIC or Facility Manager: | Phone Number: |
| If you handle controlled substances, complete the following as applicable and submit a copy of your DEA registration. | |
| DEA Registration #: | Registration Expiration Date: |
| Application Date (If recently applied): | |

Check the answer to each of the following questions:

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| MANUFACTURING PRACTICE |
| Do you maintain the building, operate the equipment, and administer the controls, records and methods used for, and in connection with, the manufacturing, processing, packing, labeling, holding, and distributing of all prescription drugs in conformity with current good manufacturing practice pursuant to the criteria set forth in the provisions 21 C.F.R. 211.1 TO 211.208? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| WHOLESALE PRACTICE |
| 1. Does the facility meet the following standards for the storage and handling of prescription drugs and the establishment and maintenance of prescription drug distribution records: |
| a) Is this facility of suitable size and construction to facilitate cleaning, maintenance and proper operations? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| b) Does the facility have storage areas that are designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| c) Does the facility have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated or that are in immediate or sealed secondary containers that have been opened? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| d) Is this facility maintained in a clean and orderly condition? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| e) Is this facility free from infestation by insects, rodents, birds, or vermin of any kind? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

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| Name of Manufacturer/Wholesaler: | |
| 2. Does this facility meet the following security and general provisions: | |
| a) Is access from the outside kept to a minimum and well-controlled? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| b) Is the outside perimeter of the facility well-lit? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| c) Is entry into areas where prescription drugs are held limited to authorized personnel? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| d) Is the facility equipped with an alarm system to detect any entry after hours? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| e) Is the facility equipped with a security system to provide protection against theft and diversion? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| f) Are computers, electronic records and other documents kept under security to prevent tampering with the records? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| 3. Will all prescription drugs be stored at appropriate temperatures and conditions in accordance with label requirements or in accordance with requirements in the current edition of the official compendium? | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | |
| 4. Do you maintain and enforce written policies and procedures which include all of the following? | |
| a) Making sure the oldest approved stock of a prescription drug product is distributed first? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| b) Handling recalls and withdrawals of prescription drugs? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| c) Making sure that wholesale drug distributors prepare for, protect against, and handle, any crisis that affects security or operation of any facility in the event of strike, fire, flood, other natural disaster, or other emergency situations? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| d) Ensuring that any outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or destroyed? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| 5. Do you maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs which include all of the following: | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | |
| a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of location from which the drugs were shipped? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| b) The identity and quantity of the drugs received and distributed or disposed of? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| c) The dates of receipt and distribution or other disposition of the drugs? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| 6. Are inventories and records maintained and available for inspection for a period of two years after disposition of the drugs? | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | |
| 7. Do you maintain a list of officers, directors, managers, and other persons who are in charge of wholesale drug distribution, storage, and handling that includes a description of their duties and a summary of their qualifications? | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | |
| 8. Do all employees have sufficient education, training, and experience to perform their assigned functions in a manner that assures that the drug product quality, safety and security is maintained at all times? | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | |

CERTIFICATION

I certify under penalty of perjury that I have been authorized by the applicant to complete this compliance checklist, and that the answers and statements given are complete, true and correct.

Printed Name of Authorized Representative of Owner

Signature of Authorized Representative of Owner

Date

Title

Telephone Number

Submit the application and compliance checklist along with your check or money order made payable to the "State of Michigan" to:

Michigan Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Licensing Division - Pharmacy
PO Box 30670
Lansing, MI 48909